

REMARKS

A. AMENDMENTS TO THE CLAIMS

Claims 1-19, 26-36, and 45-61 are pending. Claims 26-36 and 45-61 are withdrawn from consideration, claim 13 is allowed, and claims 1-12 and 14-19 are currently under examination.

Claim 1 has been amended to clarify that the antibody or fragment thereof does not bind to a non-phosphorylated amino acid sequence as set forth in SEQ ID NO: 5, SEQ ID NO: 6, or SEQ ID NO: 3. Support for the amendment can be found at page 17, lines 14-16 of the application-as-filed. Claims 2, 3 and 7-10 have been amended for clarity. No new matter has been added by way of the amendments.

B. THE OFFICE ACTION

The Office maintained the rejection of claims 1-4, 6-10, 12, 14-16, and 19 under 35 U.S.C. § 102(e) for assertedly being anticipated by U.S. Patent No. 6,822,138 (“Schreiber”). The rejection of claims 1-10, 12, and 14-19 under 35 U.S.C. § 103(a) for assertedly being obvious over Schreiber in view of Green, *J Immun Methods*, 231, 11-23 (1999) (“Green”) and Owens et al., *J Immun Methods*, 168, 149-165 (1994) (“Owens”) was maintained. Claim 11 was objected to without further explanation. Representative of Applicants, Lance Shaner, requested clarification of the objection to claim 11 via telephone on August 23, 2011. Applicants thank Examiner Wen for clarifying that claim 11 was objected to for depending from a rejected claim but was otherwise allowable.

C. THE REJECTION UNDER 35 U.S.C. § 102(e) SHOULD BE WITHDRAWN

Claims 1-4, 6-10, 12, 14-16, and 19 were rejected under 35 U.S.C. § 102(e) for assertedly being anticipated by Schreiber. The rejection is respectfully traversed for the reasons set forth below.

To anticipate the pending claims, Schreiber must teach each and every element of the rejected claims. *See, e.g., Verdegaal Bros. v. Union Oil Co. of CA*, 814 F.2d 628, 631 (Fed. Cir. 1987). Claims 1-4, 6-10, 12, 14-16, and 19 are directed to a polyclonal, monoclonal, chimeric, humanized, human or anti-anti-idiotype antibody or fragment thereof

(or a pharmaceutical composition comprising the antibody or fragment thereof) capable of specifically binding an amino acid sequence set forth in SEQ ID NOs: 5, 6, or 3 comprising a phosphorylated threonine at amino acid position 559 of SEQ ID NO: 5, position 26 of SEQ ID NO: 6, or position 11 of SEQ ID NO: 3, wherein the antibody or fragment thereof does not bind the non-phosphorylated amino acid sequence set forth in SEQ ID NO: 5, SEQ ID NO: 6, or SEQ ID NO: 3. The Office asserted that the claims “[do] not require the antibody to bind to a specific epitope that contains phosphorylated T559 but only that the sequence has to have [a] phosphorylated T559 residue.” See Office Action, p. 10. The Office concludes that because SEQ ID NO: 5 is a 947 amino-acid-long polypeptide, the polyclonal antibody of Schreiber would bind to some epitopes in SEQ ID NO: 5. Thus, the Office found that Schreiber anticipated the claims.

As amended, the pending claims are directed to an antibody or fragment thereof being capable of specifically binding the amino acid sequence set forth in SEQ ID NO: 5, SEQ ID NO: 6, and/or SEQ ID NO: 3, wherein the amino acid sequence comprises a phosphorylated threonine at amino acid position 559 of SEQ ID NO: 5, position 26 of SEQ ID NO: 6, or position 11 of SEQ ID NO: 3, and wherein the antibody or fragment thereof does not bind the non-phosphorylated amino acid sequence set forth in SEQ ID NO: 5, SEQ ID NO: 6, or SEQ ID NO: 3. Schreiber apparently discloses a genus of antibodies that bind NIK, but does not teach each and every feature of the claim-recited antibody or antibody fragment. Specifically, Schreiber does not disclose an antibody that (1) specifically binds the phosphorylated amino acid sequence set forth in SEQ ID NO: 5, SEQ ID NO: 6, and/or SEQ ID NO: 3 and that (2) does not bind the non-phosphorylated amino acid sequence set forth in SEQ ID NO: 5, SEQ ID NO: 6, or SEQ ID NO: 3. Schreiber cannot anticipate the amended claims because the Office cannot read out, or ignore, the claim requirement for specific binding, *i.e.*, binding the phosphorylated forms of SEQ ID NO: 5, SEQ ID NO: 6, and/or SEQ ID NO: 3 but not the non-phosphorylated forms of SEQ ID NO: 5, SEQ ID NO: 6, and/or SEQ ID NO: 3. The Office has not provided evidence or a reasonable scientific basis for asserting that Schreiber’s antibodies would specifically bind a phosphorylated amino acid sequence set forth in SEQ ID NOs: 5, 6, or 3 and not bind the non-phosphorylated amino acid sequence set forth in SEQ ID NO: 5, SEQ ID NO: 6, or SEQ ID NO: 3. Moreover, Examples

2 and 3 and Figures 4 and 5 demonstrate that the claimed antibodies recognize only the phosphorylated version of NIK.

Accordingly, Schreiber fails to explicitly or inherently disclose each element of any of the rejected claims drawn to anti-NIK antibodies specifically binding phosphorylated forms of NIK. Thus, the rejection of claims 1-4, 6-10, 12, 14-16, and 19 under 35 U.S.C. § 102(e) over Schreiber has been rendered moot and should be withdrawn.

D. THE REJECTION UNDER 35 U.S.C. § 103(a) SHOULD BE WITHDRAWN.

The Office rejected claims 1-10, 12, and 14-19 under Section 103(a) for assertedly being obvious over Schreiber in view of Green and Owens. The rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the Office must establish that the art disclosed or suggested each claim-recited element, that there is a reason to modify a teaching or to combine teachings of multiple references, and that one of skill must have a reasonable expectation of success in practicing the claimed subject matter. *See KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731 (2007).

As noted above, claim 1 has been amended to recite “wherein the antibody or fragment thereof does not bind the non-phosphorylated amino acid sequence set forth in SEQ ID NO: 5, SEQ ID NO: 6, or SEQ ID NO: 3.” As amended, the rejected claims are drawn to antibodies or fragments thereof that specifically bind phosphorylated NIK but do not bind non-phosphorylated NIK. Schreiber does not disclose, expressly or inherently, or suggest an antibody that specifically binds phosphorylated NIK but not non-phosphorylated NIK. Green and Owens were cited as purportedly describing human, humanized, and chimeric antibodies or providing motivation for generating monoclonal antibodies, and these references fail to cure the deficiencies of Schreiber in disclosing or suggesting each element of any of the rejected claims. Moreover, the instant application teaches use of a phospho-peptide (SEQ ID NO: 3 phosphorylated at T11, corresponding to T559 of SEQ ID NO: 5) to elicit antibodies specifically binding phosphorylated NIK and not non-phosphorylated NIK. See Example 1. Schreiber does not disclose or suggest using a phospho-peptide of any kind to elicit

antibodies and didn't disclose or suggest the claimed antibodies specifically binding phosphorylated NIK and not non-phosphorylated NIK. Thus, the Office has not established a *prima facie* basis for rejecting the claims under § 103(a) because the Office has not established that the prior art discloses or suggests all the elements of the claims.

Accordingly, the rejection of claims 1-10, 12, and 14-19 under 35 U.S.C. § 103(a) over Schreiber in view of Green and Owens, considered alone or in combination, has been obviated and should be withdrawn.

In addition, the Office has not provided a reason to modify or to combine teachings of the cited references to arrive at the claimed invention. Schreiber, Green and Owens are all silent in regard to preparation of anti-NIK antibodies that specifically bind to phosphorylated NIK and do not bind to non-phosphorylated NIK. As such, the Office has not provided a reason for combining, or modifying, the cited references to arrive at the claimed subject matter.

Finally, the Office has not established that there would have been a reasonable expectation of success in combining the cited references to arrive at the claimed invention. The combination of Schreiber, Green and Owens does not disclose or suggest each element of any rejected claim in failing to disclose or suggest an antibody or fragment thereof that specifically binds phosphorylated NIK but does not bind non-phosphorylated NIK. Further, the Office has not established a reason to combine or modify the cited references to arrive at the claimed subject matter. With a missing claim element and no reason to combine or modify the cited references, one of ordinary skill in the art could not have had a reasonable expectation of successfully realizing the claimed subject matter. Accordingly, the rejection of claims 1-10, 12, and 14-19 under 35 U.S.C. § 103(a) over Schreiber in view of Green and Owens, considered alone or in combination, has been overcome-in-part and rendered moot-in-part and the rejection should be withdrawn.

E. CONCLUSION

Applicants submit that the pending application is in condition for allowance. The Examiner is invited to contact the undersigned attorney by telephone if there are issues or questions concerning this submission that might be efficiently resolved in that manner.

Respectfully submitted,

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